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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/663,454	09/15/2003	James D. Murray	UCAL-286	4027
24353	7590	11/02/2005	EXAMINER	
BOZICEVIC, FIELD & FRANCIS LLP 1900 UNIVERSITY AVENUE SUITE 200 EAST PALO ALTO, CA 94303			HAMA, JOANNE	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Advisory Action</b> <b>Before the Filing of an Appeal Brief</b>	Application No.	Applicant(s)	
	10/663,454	MURRAY ET AL.	
	Examiner	Art Unit	
	Joanne Hama, Ph.D.	1632	

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 06 October 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to or on the same day as filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 6 months from the mailing date of the final rejection.  
b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.

Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☒ The Notice of Appeal was filed on 06 October 2005. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☐ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because
- (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
(b) ☐ They raise the issue of new matter (see NOTE below);  
(c) ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
(d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
5. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.  
6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
7. ☒ For purposes of appeal, the proposed amendment(s): a) ☐ will not be entered, or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
The status of the claim(s) is (or will be) as follows:  
Claim(s) allowed: \_\_\_\_\_.  
Claim(s) objected to: \_\_\_\_\_.  
Claim(s) rejected: 1,3,5,15,17-21,33,35,36 and 38-43.  
Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because: see attached.  
12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_.  
13. ☐ Other: \_\_\_\_\_.

Continuation of 5. Applicant's reply has overcome the following rejection(s): Rejection of claims 3, 5, 39-43 under 35 USC 112, 2nd parag. has been overcome. Applicant has amended the claims.

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## Request for Reconsideration/Other:

The amended claims submitted by the Applicant October 6, 2005 are not in condition for allowance. The Applicant has also submitted Remarks, October, 6, 2005, addressing the issues concerning the instantly filed claims.

The instantly filed claims remain rejected under 35 U.S.C. 112, first parag. Enablement for reasons of record, September 2, 2004 and April 6, 2005. With regards to the scope of "Fatty acid desaturase genes" (Applicant's Remarks, pages 8-9), the Examiner does not find the arguments persuasive. As stated in the Office Action of April 6, 2005, an artisan cannot reasonably predict whether any fatty acid desaturase from any species of mammal would necessarily have the same enzymatic activity as it has in the original animal. While the Applicant points out that minimally, the tissue of the transgenic non-human mammal comprises a level of MUFA that is 5% higher than that of the level of MUFA in the same tissue of a non-transgenic mammal of the same (Applicant's Remarks, page 8, 5<sup>th</sup> parag.), the point that the Examiner was trying to make was that the art (e.g. see Hammer et al. citation) teaches that an artisan cannot predict that heterologous proteins would have any activity in any transgenic non-human mammal. The specification has not provided guidance as to how an artisan would obtain any fatty acid desaturase from any species of animal and predictably know that it would have activity in a heterologous animal. With regards to the Applicant's argument that the claimed invention is enabled for making polyunsaturated fatty acids (PUFAs) (Applicant's response, page 9), the Examiner does not find the argument convincing for reasons of record, April 6,

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2005, page 7). While the Applicant indicates that stearyl-CoA (SCD) catalyzes the formation of double bonds, such that conjugated linoleic acid (CLA) can be generated, CLA is not a PUFA. As such, the specification has not provided any guidance as to how the claimed invention makes any PUFA.

With regards to the issue of "Tissue-specific promoters" (Applicant's Remarks, pages 9-10) and "Food Products" (Applicant's Remarks, page 11), the Examiner does not find the Applicant's argument persuasive. As discussed in the previous Office Actions, the art teaches the unpredictability in using any heterologous promoter in any transgenic non-human mammal. As such, because the art teaches unpredictability in obtaining heterologous promoter, an artisan cannot necessarily obtain the transgenic non-human animal, wherein the non-human animal expresses the transgene in a tissue of interest and can subsequently be eaten as food.

With regards to the "Method for producing a non-human transgenic animal" wherein the non-human animal is made by nuclear transfer (i.e. cloning) (Applicant's Remarks, pages 10-11), the Examiner has reconsidered the rejection. With regards to this issue, the method is enabled. However, it is noted that the method (e.g. claim 18) is not enabled for the full scope for issues such as scope of promoter and of any fatty acid desaturase, as discussed in the prior Office Actions.

The instant claims also remain rejected under 35 USC 112, first parag., Written Description, for reasons of record, September 2, 2004 and April 6, 2005. As described in the previous Office Actions, the specification does not provide

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guidance to the artisan to obtain any fatty acid desaturase because the genus encompasses a large number of species that would have different structures.

Also, the previous Office Actions indicate that the claims are broad for any tissue specific promoter. As the Applicant provides no additional Written Description regarding these issues, the rejection remains.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.


Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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JH



**DAVE TRONG NGUYEN**  
**SUPERVISORY PATENT EXAMINER**